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Ralph Nader, Founder

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Dockets Management Branch (HFA-305)
Food and Drug Administration, Rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Medical Device Incident Reporting, Docket No. 93N-0072

Public Citizen's Health Research Group offers the following comments regarding medical device problem reporting. It has been over a year and a half since FDA published a "tentative final rule" in the Federal Register (Docket No. 91-N0295, November 26, 1991), regarding medical device reporting. Public Citizen submitted comments on the proposed rule on February 28, 1992 (enclosed). FDA held an open public meeting to further address statutory, regulatory, compliance, and training issues related to medical device problem reporting (MDR) on July 13, 1993, and is soliciting comments until July 28, 1993. We are most concerned about apparent industry opposition to the regulation which requires manufacturers and distributors to annually certify that they have submitted to FDA all reportable adverse device reports, or that they did not receive any such reports. We strongly urge FDA to keep the tentative rule as is, when publishing final reporting regulations later this year. This way, manufacturers and distributors will not only have to certify that a certain number of reports were submitted to FDA, but also, that the number submitted did, in fact, include all reportable events. And they will not be able to merely certify that they submitted no reports over the prior year; they will be required to certify that they did not submit any reports because they received none.

The Safe Medical Devices Act of 1990 (SMDA) was enacted to correct problems with the implementation and enforcement of the Medical Device Amendments of 1976. The 1976 law required manufacturers and distributors to report to FDA product defects and adverse effects of the firms' devices. However, serious under-reporting of device-related reportable events was discovered, and in an effort to increase compliance, a certification requirement was included in the SMDA. Section 3(b) of SMDA states that, "[e]ach manufacturer, importer, and distributor required to make reports under subsection (a) shall submit to the Secretary annually

a statement certifying that - (1) the manufacturer, importer, or distributor did file a certain number of such reports, or (2) the manufacturer, importer, or distributor did not file any report under subsection (a)."

In its November 26, 1991 tentative final rule, the FDA's certification regulation stated that manufacturers and distributors' annual registration forms must contain a statement certifying that, "(1) The firm....has filed reports under this section during the previous 12-month period, the number of reports that were submitted to FDA, and that all MDR reportable events were submitted to FDA; or (2) The firm....did not receive any reportable events during the previous 12-month period." This regulation is entirely consistent with the statute; implicit in a law requiring certification that a certain number of reports were filed is a common-sense assumption that the number includes all adverse events reportable by law. However, manufacturers have complained that the proposed regulation explicitly states that companies must certify that all reportable events were submitted - language that was not in the statute. The distinction appears very technical, yet it is extremely important.

If FDA retreats from its position in the proposed regulations, there will be two significant repercussions: (1) the agency will send the wrong message, namely that it has relaxed its pressure on industry to be accountable for MDR reporting, and (2) the agency will nullify the intent of the statute. For example, a manufacturer may receive 1,000 reports of deaths, serious injuries, and malfunctions related to its devices, but to avoid triggering an FDA inspection, it may submit only half of them, or only the deaths and serious injuries. Later, when completing the annual certification form, this manufacturer could honestly certify, "I submitted 500 adverse event reports last year." The failure to submit all reportable events may never be discovered by FDA. However, even if this manufacturer <u>is</u> caught, a strict reading of the statutory language indicates that it may only be sanctioned for failure to submit reports, and not for a false statement (No company has ever been subject to final civil or criminal sanctions for MDR violations).

But, if the FDA proposed regulation becomes final, that same manufacturer could be found in violation of 21 U.S.C. section 331(q)(2), which states that, "[w]ith respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect" is prohibited. The manufacturer could then be subject to one year imprisonment and/or a $1,000 fine (21 U.S.C. 333(a)(1)), and, if fraud is proved, three years imprisonment and/or a $10,000 fine (21 U.S.C. 333(a)(2)). Or, it could be subject to civil penalties not to exceed $15,000 for each violation or $1,000,000 for all violations adjudicated in a single proceeding (21 U.S.C. 333(f)(1)(A)).

Thus, there is a much greater likelihood of a manufacturer or distributor being punished if it is found to have submitted a false

statement in a certification to a government agency, in addition to the original MDR violation. And, there is much greater incentive for the manufacturer to submit the reports in the first place, which is, after all, the overall intent of the law's MDR provision. That is why FDA should adhere to its prior position that the annual certification must state that all reportable adverse events were reported, or that the company received no reports.

> The House Report, submitted with the SMDA, states that:
> "[t]he certification requirement is included on the recommendation of the General Accounting Office (GAO) as an important means of increasing the effectiveness of the MDR system. In a report prepared for the subcommittee, the GAO recommended that all firms that manufacture or import medical devices submit an annual statement indicating either that they filed no MDR reports during the calendar year because they did not receive or otherwise become aware of information concerning MDR-reportable events, or that they filed a specific number of reports on each type of reportable event and that the firm received or became aware of information concerning only these events."

H. Rep. No. 101-808, p. 23. Furthermore, the House Conference Report indicates that, "[t]he conference agreement follows the House bill with several exceptions," and the certification section is not among those exceptions.

FDA has used its discretion in a manner fully consistent with Congress's intent, as evidenced by this legislative history. "A statute is not to be read over literally. It has long been settled that acts of Congress must be interpreted in light of the spirit in which they were written and the reasons for their enactment." General Service Employees Union Local No. 73 v. NLRB, 578 F.2d 361, 366 (D.C. Cir. 1978) (footnotes omitted). Accord Lynch v. Overholser, 369 U.S. 705, 710 (1962); National Woodwork Mfrs. Ass'n v. U.S., 386 U.S. 612 (1967). See also Crandon v. U.S., 110 S. Ct. 997, 1001 (1990) ("In determining the meaning of a statute, we look not only to the particular statutory language, but to the design of the statute as a whole and to its object and policy"). An objective of Congress in enacting the SMDA was to improve compliance with MDR regulations. FDA's proposed regulation of November 26, 1991 is well within the agency's discretion in its efforts to implement that goal, and should be left intact when final regulations are published, something which should occur as soon as possible.

Joanne C. Mott, R.N., J.D.
Health Research Group
Public Citizen

Sidney M. Wolfe, M.D.
Director, Health Research Group
Public Citizen